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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/599,136	01/24/2007	Robert Gordon Hood	9931-012US	4863
79526	7590	11/30/2009	EXAMINER	
DeMont & Breyer, LLC			WOOD, ELLEN S	
100 Commons Way, Ste. 250				
Holmdel, NJ 07733			ART UNIT	PAPER NUMBER
			1794	
			MAIL DATE	DELIVERY MODE
			11/30/2009	PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	10/599,136	HOOD ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	ELLEN S. WOOD	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) Responsive to communication(s) filed on 04 September 2009.  
 2a) This action is **FINAL**.                    2b) This action is non-final.  
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) Claim(s) 1-2, 40-43, and 45-80 is/are pending in the application.  
 4a) Of the above claim(s) 53-80 is/are withdrawn from consideration.  
 5) Claim(s) \_\_\_\_\_ is/are allowed.  
 6) Claim(s) 1-2, 40-43 and 45-52 is/are rejected.  
 7) Claim(s) \_\_\_\_\_ is/are objected to.  
 8) Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) The specification is objected to by the Examiner.  
 10) The drawing(s) filed on 20 September 2006 is/are: a) accepted or b) objected to by the Examiner.  
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
 a) All    b) Some \* c) None of:  
 1. Certified copies of the priority documents have been received.  
 2. Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.  
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | Paper No(s)/Mail Date. _____ .                                    |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>10/07/2009; 02/07/2007; 09/20/2006</u> . | 5) <input type="checkbox"/> Notice of Informal Patent Application |
|   | 6) <input type="checkbox"/> Other: _____ .                        |

## DETAILED ACTION

### ***Election/Restrictions***

1. Applicant's election without traverse of Group I, claims 1-2, 40-43 and 45-52 in the reply filed on 09/04/2009 is acknowledged.

### ***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-2, 40, 46 and 49 are rejected under 35 U.S.C. 102(b) as being anticipated by Houston et al. (US 2002/0179166, hereinafter “Houston”).

In regards to claim 1, Houston discloses a helix structure 100 comprising ribs 1a-c which are disposed in a helical flow guiding formation along the longitudinal axis of the structure 100 [0047 and fig. 1]. Helix structure 100 further has smaller frame components which support the orientation of the ribs 1a-c [0047]. The helix structure 100 is fitted over a graft 3 [0047 and fig. 3]. The graft is considered the tubular conduit and comprises PTFE material, which is sufficiently malleable to be shaped by ribs 1a-c [0048]. Other medical plastics or plastifiable material which has the malleable characteristic may also be used [0048].

A cylindrical wire mesh structure 400 comprises flow guidance forming wires 13a-c interspersed with support wires 14a,b which are orientated in the same direction

and more or less parallel to the nearest flow guidance forming wire 13a-c [0054 and figs. 7A-7B], thus a external helical formation.

A conduit, adapted for flow of a fluid having characteristics and velocity and having a given diameter, by apparatus that imposes, maintains or reinforces a flow guiding formation internally of the conduit, the apparatus comprising a helical structure to cause helical, rotational flow eliminating or reducing turbulence and/or eliminating or reducing dead flow regions in the flow, when used for such a fluid flow [0005]. It would be inherent that the internal helix angle would be different from the external helix angle, because the angle of the helical flow formation is determined from the internal dimensions of the conduit, the fluid mass flow of the conduit, the pressure drop along the conduit and the turbulent kinetic energy within the conduit [0006].

In regards to claim 2, Houston discloses that the invention may also be utilized for stent grafts [0026].

In regards to claim 40, Houston discloses that the structure could be placed inside or outside the blood vessel to impose, maintain and/or reinforce a flow guiding formation through the blood vessel [0025], thus a vascular stent.

In regards to claim 46, Houston discloses that the internal helical protrusion is 8<sup>0</sup> [0063].

In regards to claim 49, Houston discloses that the tubular portion is made from PTFE [0048].

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4. Claims 1,2,40,41,43,45-49 and 52 are rejected under 35 U.S.C. 102(e) as being anticipated by Caro et al. (US 2007/0021707, hereinafter “Caro”).

In regards to claim 1, Caro discloses a graft comprising flow tubing having a tubing portion defining a flow lumen [0013]. The tubing is made from flexible material [0038]. The tubular wall may further comprise a reinforcement that is helical wound with a large helix angle around the tubular wall [0052]. The tubing portion is the helical protrusion located around the inside of the tubular portion [0015]. The helical tubing portion improves flow characteristics [0016]. The helical tubing portion may extend over the entire length of the tubing [0026].

In regards to claims 2 and 40, Caro discloses that the graft is used for vascular access grafts [0043].

In regards to claim 41, Caro discloses that the helically arranged elongate member serves to deform the tubular wall to the shape with the longitudinally extending helical cavity [0068].

In regards to claim 43, Caro discloses that the elongate member may be of a composite construction that is made of a biocompatible polymer which can soften sufficiently when heated to bond to the tubular wall [0072], thus sintered.

In regards to claim 45, Caro discloses that the internal helical protusions is less than 65<sup>0</sup> [0021] and the externally helically wound support is close to 90<sup>0</sup> [0016], thus the helix angle of the external helical formation is greater than the helix angle of the internal helical protrusion.

In regards to claim 46, Caro discloses that the helix angle of the internal helical protrusion is preferably less than or equal to  $65^0$ , preferably less than or equal to  $55^0$ ,  $45^0$ ,  $35^0$ ,  $25^0$ ,  $20^0$ ,  $15^0$ ,  $10^0$ , or  $5^0$  [0021].

In regards to claims 47 and 48, Caro discloses that the tube may be externally supported with helically wound (with a very large helix angle, close to  $90^0$ ) polypropylene [0016].

In regards to claim 49, Caro discloses that the tubing is made of ePTFE [0056].

In regards to claim 52, Caro discloses that the elongate member may be of a composite construction that is made of a biocompatible polymer which can soften sufficiently when heated to bond to the tubular wall [0072], thus sintered.

### ***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

6. Claims 42 and 50 are rejected under 35 U.S.C. 103(a) as being unpatentable over Caro et al. (US 2007/0021707, hereinafter “Caro”) in view of Murch (US 2003/0225453).

Caro discloses a graft comprising flow tubing having a tubing portion defining a flow lumen [0013].

Caro is silent with regards to the axially extending deformation helix being made of polyurethane.

Murch discloses a graft that is made of an inner and outer layer fused together and the inner layer is made of expanded PTFE (ePTFE) [0027]. The outer layer may be made out of polyurethane [0027].

It would be obvious to one of ordinary skill in the art to substitute the polyurethane outer layer of Murch with the outer helical layer of Caro, because the polyurethane layer of Murch improves the strength of the device and further reduces the size of the device [Murch 0027].

7. Claim 51 is rejected under 35 U.S.C. 103(a) as being unpatentable over Caro et al. (US 2007/0021707, hereinafter “Caro”) in view of McHaney et al. (US 5,827,327, hereinafter “McHaney”).

Caro discloses a graft comprising flow tubing having a tubing portion defining a flow lumen [0013].

Caro is silent with regards to the axially extending deformation helix being made of polyurethane.

McHaney discloses a vascular graft which comprises carbon as an integral part of the wall of the tubular graft (col. 1 lines 8-14).

It would be obvious to one of ordinary skill in the art to combine the carbon coating of McHaney with the internal wall of the vascular graft of Caro, because the carbon coating of McHaney provides a vascular graft that exhibits a less thrombogenic

blood contact surface with a minimal amount of carbon leaching and the carbon containing graft facilitates the binding of a time releasable bioactive substances, such as an anticoagulant or antimicrobial agent, to the graft (col. 2 lines 29-40).

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELLEN S. WOOD whose telephone number is (571)270-3450. The examiner can normally be reached on M-F 730-5 with every other Friday off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Rena Dye can be reached on (571)272-3186. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Rena L. Dye/  
Supervisory Patent Examiner, Art Unit 1794